EPC Pilot Project: A Dual Approach To Facilitate Health Systems Uptake of Evidence Synthesis Reports. Anxiety in Children



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Prepared by: Mayo Clinic Evidence-based Practice Center Rochester, MN

Investigators:

Allison S. Morrow, B.A. Stephen P. Whiteside, Ph.D., L.P. Leslie Sim, Ph.D., L.P. Juan P. Brito, M.B.B.S. Zhen Wang, Ph.D. M. Hassan Murad, M.D. M.P.H.

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Key Messages

- Findings: A health system decision aid and an encounter decision aid were shown to be feasible and effective tools that can provide health systems with contextual and implementation information on the treatment of anxiety in children.
- Lessons learned for EPC Program: Comparative effectiveness evidence syntheses often do not have sufficient information that allows decision-making and implementation of evidence. This includes information on costs, resources, patients' values, acceptability and feasibility of interventions. Additional synthesis of study characteristics and intervention components is often needed.
- Utility for health systems: A dual approach that caters to the needs of both health system decision-makers and the clinician-patient dyad may facilitate uptake of evidence synthesis reports by health systems.

This report is based on research conducted by the Mayo Clinic Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No.290-2015-00013-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodologic issues in systematic reviews. These methods research projects are intended to contribute to the research base in and be used to improve the science of systematic reviews. They are not intended to be guidance to the EPC program, although may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The reports undergo peer review prior to their release as a final report.

If you have comments on this Methods Research Project they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

Gopal Khanna, M.B.A.	Arlene Bierman, M.D., M.S.
Director	Director
Agency for Healthcare Research and Quality	Center for Evidence and Practice
	Improvement
	Agency for Healthcare Research and Quality
Stephanie Chang, M.D., M.P.H.	David W. Niebuhr, M.D., M.P.H., M.Sc.
Director	Task Order Officer
Evidence-based Practice Center Program	Center for Evidence and Practice
Center for Evidence and Practice Improvement	Improvement
Agency for Healthcare Research and Quality	Agency for Healthcare Research and Quality

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Structured Abstract

Objective. To develop tools that can facilitate uptake of evidence synthesis reports by health systems.

Data Source. We used a published evidence report on anxiety in children. We conducted a nonsystematic review of Pubmed, searched the Internet and interviewed experts and other stakeholders for literature on factors essential for treatment decision-making.

Methods. We followed a dual approach in which we developed two tools, one for the health system (based on the Evidence to Decision Framework) and the second for the clinical encounter (a shared decision-making tool). The tools provided contextual and implementation information for stakeholders.

Results. A health system decision aid (DA) was produced as a hard copy and provided information on which patients are candidate for treatment, values and preferences, costs and resources, acceptability, impact on health equity, feasibility, drug dosing, psychotherapies other than cognitive behavioral therapy, remission rates and prognosis of anxiety in children. Health system stakeholders found the DA useful and generalizable to other conditions. The encounter DA was produced as cards containing information on issues that drive treatment decisions (effect on symptoms, effect on function, treatment burden, side effects and cost). Patients and parents prioritized the cards and chose the order in which these issues were discussed with clinician. The encounter DA was found to be helpful by patients, parents and clinicians.

Conclusion. A dual approach addressing health system stakeholders as well as clinicians and patients can provide practical information beyond what is traditionally contained in evidence synthesis reports. This approach is likely feasible and may facilitate uptake of evidence reports by health systems.

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Appendixes (posted separately)

Appendix A. Health System Decision Aid http://www.mayo.edu/pmts/mc3100-mc3199/mc3187-01.pdf

Appendix B. Encounter Decision Aid http://www.mayo.edu/pmts/mc3100-mc3199/mc3187-02.pdf

Background

One in eight children is diagnosed with an anxiety disorder.¹ Anxiety can interfere with a child's social, emotional and academic development and lead to additional psychology diagnoses.^{2, 3} There are multiple treatments for childhood anxiety disorders including medications such as selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, benzodiazepine, and tricyclic antidepressants.⁴ Cognitive behavioral therapy (CBT) is the main nonpharmacological anxiety treatment; which can also be used in conjunction with medications.⁵⁻⁷ Choosing between the available treatments can be challenging at all levels of healthcare decision-making, including health system stakeholders, clinicians, parents, and children.

When evidence is synthesized to help in making such decisions (such as the recent AHRQ comparative effectiveness review about Anxiety in Children),⁸ synthesis usually focuses on relative benefits and harms, and does not include practical information needed by health systems to make the decision at hand.⁹ Health systems, patients and clinicians, need additional information to make a decision and act on evidence. AHRQ has started an initiative to determine strategies to improve uptake of evidence reports by health systems. This process requires knowledge of what information health systems require; particularly which information is needed that is not currently available in the evidence reports; and which format of delivery is most useful to health systems.

Therefore, this pilot project aims to develop tools that help health systems make decisions based on evidence produced by evidence synthesis programs. Specifically, we want to produce prototypes of tools that AHRQ Evidence-based Practice Centers (EPC) can use to transform the comparative effectiveness evidence into formats most conducive for implementation by health systems.

Goal/Objective

The overarching goal of this pilot project is to develop tools that can be used by health systems to consume evidence. Under this proposition, we have the following objectives:

1. Develop prototype of tools, realizing the need for subsequent validation and testing that is beyond the scope of this pilot project.

2. Obtain feedback from stakeholders about the usefulness of the tools.

3. Provide AHRQ with description of the approach followed for development and implementation of the tools and required skills and resources.

4. Provide AHRQ with recommendations to the EPC Program about changes necessary for the current reports that facilitate the production of similar tools for other topics.

Methods

The underlying hypothesis followed in this project is that health systems require tools to support decision-making along the continuum of care. Therefore, tools need to support decision-making of the health system (i.e., those responsible about service line offering, formulary choices, staffing and environment of care determinations) and for decision-making within the clinical encounter (i.e., patient-physician dyad). We have hypothesized that addressing one of these two decision-making modes, is insufficient. Based on this hypothesis, we developed two tools:

- Tool 1: Evidence-to-decision framework for health system decision makers. In this report, we refer to this tool as a "*Health System Decision Aid*".
- Tool 2: Shared decision-making tool (also called a decision aid) for the patient-clinician dyad. In this report, we refer to this tool as an "*Encounter Decision Aid*".

Health System and Representative Description

The Health System

We engaged the Mayo Clinic Health System. This is a family of clinics, hospitals and other health care facilities serving more than 60 communities in Minnesota, Wisconsin and Iowa. Founded in 1992, the system links the expertise of Mayo Clinic with health care providers in local communities to offer patients a full spectrum of health care options, with more than 100 medical services and specialties available throughout the system

Stakeholders/Health Systems Representatives

Representatives for the Health System Decision Aid

We engaged four representatives from the health system:

Stephen P. Whiteside, Ph.D., L.P. is the Chair of the Convergence Child Specialty Council, which is the entity in the health system that directs mental health efforts and sets standards and practice algorithms. He is also the Director of the Childhood Anxiety Clinic in Rochester. The Council supports mental health practice at 28 sites; of which, 23 have a least one provider that works with child mental health.

Two members of the Mayo Clinic Pharmaceutical Formulary Committee Neurology and Psychiatry Task Force, responsible for making decisions on which drugs can be used in the Mayo Clinic Health System.

Bruce Sutor, M.D., is the chair for clinical practice in the Department of Psychiatry and Psychology at Mayo Clinic.

Representatives for the Encounter Decision Aid

We engaged nine end users of the decision aid. This included two patients (one parent and child pair who presented for assessment of anxiety and to explore treatment options), and seven clinicians (two psychologists, and one psychiatrist from the Mayo Clinic Rochester's Anxiety Clinic and three psychologists from other health system locations (LaCrosse, WI, Eau Claire, WI and Albert Lea-Austin, MN), and one psychologist from Mayo Clinic Rochester, who is not a member of the Anxiety Clinic).

Consistent with Office of Management and Budget guidance, we always maintained fewer than 9 individuals being asked the same question.

Process Description

Framework

The development process of the system decision tool followed the established framework for decision making called Evidence to Decision (EtD) framework developed by The GRADE Working Group (Grading of Recommendations, Assessment, Development and Evaluation).¹⁰ This framework presents 7 factors essential for decision-making: certainty of the evidence (strength of evidence), balance of benefits and harms, patient values, costs and resources, feasibility, acceptability and equity.

The development of the encounter decision aid followed the principles of shared-decision making and the design characteristics recommended for decision aids.

We did not utilize a specific implementation framework and depended on our hypothesis that for evidence to be translated in a health system, decisions need to be supported at multiple levels. Hence, we followed the dual approach of developing two tools for health systems and for patients/clinicians encounters.

Health System Decision Aid

The four health system representatives were given the EPC report and asked about what other information they require to make their decisions about choice of therapy (specifically, they were asked to simulate a decision in which they are trying to choose which drugs to cover or which psychotherapies to provide to children with anxiety in their health system). They were also asked about the design and format of the system decision aid. This feedback was mapped to, and complimented the seven factors from the EtD. Specifically, stakeholders wanted to know expected remission rates, dropout rates, costs, the inclusion criteria of treatment trials, average dosing, and effectiveness of other possible treatments not commonly used (such as non-CBT talk therapy). The majority of this information was available in the evidence report; however, it was reported in tables or appendices and wasn't presented in a prominent fashion in the report.

We searched the literature (PubMed and Google Scholar) for information on each factor as it relates to anxiety in children. This search was not systematic (ie, it was not a systematic review).

Encounter Decision Aid

A shared decision making tool was developed to aid in clinician-patient encounters when discussing treatment options for childhood anxiety. This tool was based on a previously developed and tested decision aid for diabetes.¹¹ The structure, design, and themes of the diabetes cards were modified to fit the needs of patients with anxiety and their parents. In collaboration with two psychologists, the 5 topics usually discussed when a treatment is chosen were: "reduction in anxiety symptoms, improvement in day-day function, treatment, side effects and cost." Each topic was depicted in a hard copy "card" with information that can be used during the encounter.

Clinicians were sent a letter from the Practice Convergence Chair encouraging them to use the card and describing how to use it. The letter referred users to a video showing a demonstration of how the diabetes decision aid was used in a previous randomized trial. In brief, clinicians were instructed to ask patients for the issue most important to them when making a treatment choice. The respective card will be discussed first. Then, patients were asked about the second most important issue, and so forth. Data used to complete the cards were derived primarily from the EPC report. Other information about treatment length and cost was gathered from internal health system resources. Data about side effects were taken both from the EPC systematic review and from other literature identified by the two psychologists. The cards were created in collaboration with a professional designer. Once the first draft was established, multiple revisions were made based on input from two psychologists, a patient advisory group who routinely evaluate shared decision-making products, and designers with expertise in developing decision aids.

Evaluation Methods

Considering the pilot nature of this project and the limited resources and timeframe, evaluation of the tools was done using semi-structured interviews of the original stakeholders (for the health system aid) and clinicians and patients (for the encounter decision aid).

One investigator interviewed the stakeholders and asked about four issues:

- 1. Awareness of EPC evidence synthesis products and prior use for decision-making
- 2. Usefulness of the tool in terms of supporting decision-making process.
- 3. Need for additional contextual information required for decision-making.
- 4. Generalizability of this tool/approach to other topic areas.

The questions used with health system stakeholders and patients/clinicians are listed below: Health System Decision Aid Interview Questions

- 1. Are you aware of EPC evidence synthesis products and have you used them for decision-making?
- 2. Do you think the tool is useful in terms of supporting decision-making process?
- 3. What additional contextual information is required for decision-making?
- 4. Do you think this tool is generalizable to other topic areas?

Encounter Decision Aid Questions

- 1. Do you find the decision aid useful for decision making in patient encounters?
- 2. What aspects of the cards did you find the most useful?
- 3. What would you like to change?
- 4. What situations are the most conducive for implementing the tool?

Results

Final Product Description

Health System Decision Aid

The final health system decision aid was presented as a concise exposition in a hard copy, brochure style two page document. Brevity and the use of bullet points were characteristics requested by stakeholders. The document was produced using Microsoft Publisher. It contained 6 headings (Which Patients Have Been Studied, Values & Preferences, Costs & Resources, Acceptability, Impact on Health Equity, and Feasibility). The back page provided information on drug doses, non-CBT talk therapy, remission rates and prognosis of anxiety in children. Data on inclusion criteria, average dosing, and non-CBT talk therapy were taken from the EPC report. Most of the other information was retrieved from sources outside of the original EPC report. This document is included in Appendix A.

http://www.mayo.edu/pmts/mc3100-mc3199/mc3187-01.pdf

Encounter Decision Aid

The final product was printed on six 4-by-6 heavy stock cards. One card served as a title/introduction card, and the remaining five displayed content relating to reduction in anxiety symptoms, improvement in day-day function, treatment duration, side effects and cost. This information was organized according to type of treatment (SSRI, SNRI, CBT, and combination of CBT and SSRI). Reduction in anxiety symptoms and improvement in day-day function were displayed with a scale of 1-4 using plus symbols. Treatment time was conveyed through text, as were side effects. Cost was represented with a scale of dollar signs with accompanying text for clarity. The scales for symptoms and improvement in day-to-day function were based off data from the original EPC report. Sources for costs and treatment length were gathered from Mayo Clinic resources. These cards are included in Appendix B. http://www.mayo.edu/pmts/mc3100-mc3199/mc3187-02.pdf

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Evaluation Results

Health System Decision Aid

Awareness of EPC products and prior use: Health system stakeholders were unaware of the availability of an EPC product addressing the treatments of anxiety in children. They had vague awareness of the EPC program but have not used it as a source for data to support their decisions in the past.

Helpfulness of tool: Health system stakeholders found the decision aid to be very useful because it adds information on cost, resources required to implement evidence, and feasibility of the interventions (particularly for CBT); which is not usually presented in evidence reports. They particularly liked the brevity and concise presentation. Some representatives suggested that decision tools are more valuable in decisions made in primary care settings; whereas they are less useful to highly specialized committees with extensive expertise about the topic. In terms of formulary decision, one stakeholder suggested removing information on interventions with important adverse effects; such as nefazodone (which can be associated with sudden onset liver failure and was subsequently withdrawn from the market). Other stakeholders questioned the categorization of items (suggesting moving some of them to under different categories). However, no additional information or categories of information were thought to remain needed to help a health system make a decision.

Other information needed: Health system stakeholders suggested that future tools include more information about side effects and safety concerns. They also suggested that such documents include information on pharmacoogenomics and newer data of how medication prescribing can be altered based on race and genetic make-up. They also noted that inclusion of brand names as opposed to just generic names can facilitate decision-making.

Generalizability: They considered this product generalizable to other conditions.

Encounter Decision Aid

Awareness of EPC products and prior use: Clinicians were unaware of the availability of an EPC product addressing the treatments of anxiety in children and have not used it as a source for evidence to support their decisions in the past.

Helpfulness of tool: Clinicians found the tool very helpful when they encountered patients with a single new anxiety diagnosis. They found the tool less helpful in patients with comorbidities (children with multiple diagnoses), severe symptoms, or currently already receiving anxiety treatment. They mentioned that they were unaware of some of the facts reported in the cards, such as efficacy data and cost. They thought that the cards added credibility to conversations with patients and parents. The cards also aided in taking some emotion and personal options out of the decision and focusing more on evidence. One psychologist also saw the cards as helpful in explaining evidence-based treatment to other colleagues (i.e. social workers). The cost card seemed to be the least used, insurance differences, varying regional costs of treatment, and parent's lack of concern over cost made it difficult to apply to all patients.

One parent and child (11 years old) pair were asked for their opinion on the decision aid after the anxiety assessment session with the psychologist. The parent thought that it was helpful to visualize the effects of treatment. The child stated that the scale of "pluses" improved his understanding. Other information needed: While the cards suggested that CBT had no side effects, clinicians informed patients about some drawbacks to CBT such as CBT being occasionally "hard work," "uncomfortable" or "challenging."; or may cause children to miss school. A clinician from Mayo Health System: La Crosse, WI, mentioned that the state of Wisconsin requires that information on the down sides of CBT be discussed with patients.

Clinicians commented that the length of CBT treatment in the cards (as derived from the studies included in the evidence report) was 14 sessions. In practice, the length is closer to 8-10 sessions. However changing this in the decision aid would make the function and symptom cards would be challenging because their published effects are based off of 14 sessions of treatment.

Generalizability: The decision aid format was considered to be applicable to other mental health conditions. Depression and attention deficit with hyperactivity disorder were mentioned as the most appropriate conditions.

Logistical: One psychologist thought that having another set of cards for the parents to hold would be nice. He also thought that having in a flip chart that was easily washable would be good, as many of their patients have obsessive-compulsive disorder or germ phobias. Another clinician suggested that the cards be included in the electronic medical record or as part of the assessment tool so that the information could be more easily integrated into the appointment record. The cards were distributed as sets held together by rubber bands, this made them cumbersome to use and one psychologist advised that they be held together in a more functional way.

Discussion

Utility and Applicability for Other Health Systems

Health System Decision Aid

The Health System stakeholders and formulary group review new requests for recently released medications or review the reclassification of existing medications as needed. At the

present time, they were not reviewing anxiety medications. This has limited their ability to engage in real time decision-making using the tool. Nevertheless, they have expressed interest in having such contextual information accompanying evidence synthesis reports that usually focus on efficacy. This additional information needed by health systems can be either information not commonly captured in evidence reports or information that is already available in evidence reports but are not presented in a prominent place or sufficiently synthesized. Examples of the former are information on cost, resources, acceptability, feasibility and patients' values. Examples of the latter are better synthesis of the description of the intervention and its components and explicit description of the population, its comorbidities and characteristics.

They have also observed that evidence synthesis reports commonly review existing treatments and rarely address recently approved treatments. Having evidence synthesis products (and associated tools like the one developed in this project) that address interventions just being commercially available would be most helpful to their decisions.

This health system decision aid would also be most useful for a new health system that is in the process of establishing its service lines and offerings. Health systems that have less specialized clinics and providers will likely benefit more from these tools.

Encounter Decision Aid

The encounter decision aid will likely have increased utility in health systems with limited resources, where primary care physicians are diagnosing and prescribing treatment for childhood anxiety and do not have the same expertise or knowledge base as psychologists or psychiatrists. When we implemented this tool in the Childhood Anxiety Clinic at Mayo Clinic, a highly specialized clinic with an established protocol for the treatment of childhood anxiety, we anticipated that the utilization of the tool would be lower than what is expected in less specialized or primary care settings.

Furthermore, if these clinics have an established first line treatment such as group therapy; implementation will also be less than what is expected in other settings without an established first line treatment. Another challenge relates to the fact that medications are prescribed by the psychiatrist and therapy is prescribed by the psychologist, making the decision involving more than one clinician and more than one clinical encounter. The tool will likely be very helpful for general pediatricians making referrals to a psychologist vs. a psychiatrist. Our EPC had experience in developing shared decision-making tools based on evidence synthesis reports and available designers; other EPC may not have such expertise.

Lessons Learned and Applicability for Other EPC Reports

- Health systems and clinicians have very limited awareness of AHRQ EPC products. Better dissemination to these evidence users is clearly needed.
- Health systems find most evidence synthesis reports that focus on efficacy to have limited utility and these systems desire to have additional implementation and contextual information.
- This additional information needed by health systems can be categorized as new information (not commonly captured in evidence reports) or information that is already available in evidence reports but are not presented in a prominent place (hidden in tables and appendices) or not synthesized (considered as study descriptors and briefly presented as opposed to outcome data; which are usually the focus of the reports):

- Information not usually available in reports that focus on efficacy:
 - Cost data
 - Resources required for implementation
 - Information on acceptability and feasibility
 - Information about patients values and preferences

These types of information need to be derived from a different body of literature than the one used to generate the effectiveness systematic review. It requires a different key question structure, different search terms and may need searching different databases. Examples would be cost-effectiveness analyses and modelling studies to inform cost questions, implementation literature to inform about staff training, infrastructure and healthcare delivery approaches, and qualitative research to inform questions about values and preferences. Some of this information is also not published and can vary based on geographic location; therefore, clinical content experts constitute an important source of this information.

- Information available in reports but require more synthesis or emphasis:
 - Explicit description of the intervention (dosing, duration, delivery, manpower, trade names of drugs)
 - More description of the components of complex interventions
 - Explicit description of the population, its comorbidities and characteristics
 - Increased attention to safety and harm

This information can help the health system determine which patients are candidates for receiving the interventions and inform them about the components and specifics of the intervention that they are considering to offer.

- The utility of evidence synthesis reports can be enhanced by developing tools that support the decision at two levels, the health system level and the clinical encounter level.
- Similar to what has been reported in the existing literature; health systems prefer short concise reports written in a style that is readable by clinicians and non-clinicians.
- Identifying contextual and implementation information requires grey literature and Internet search, as well as interviews with experts. Searching the traditional bibliographic databases will reveal only a small part of this information.
- A multidisciplinary team of investigators is required to develop tools that can enhance the use of evidence synthesis. These teams can include methodologists, systematic reviewers, designers, health system representatives and patient representatives.
- Creating a tool by ways of modifying an existing one makes the process more feasible and successful. We noted that creating the encounter decision aid (which was a prototype based on an existing diabetes tool) was easier and more efficient than creating the health system tool (which had no prior existing tool).
- We found no evidence to suggest that this approach (a dual tool that addresses the health system and the clinical encounter) could not be used in other disease conditions. The common EtD framework and its factors have been used across conditions and their theoretical underpinnings are transferable. Similarly, shared decision-making tools have been found to be transferrable to the extent that new research on decision aids is suggested to target design features as opposed to tools targeting special conditions.

- Most information needed by health systems map to the pre-established EtD factors: certainty of the evidence, balance of benefits and harms, patient values, costs and resources, feasibility, acceptability and equity.
- Topic refinement of evidence reports that are intended to be used by health systems should address whether additional contextual and implementation information are required. The addition of these tasks will impact the size and cost of the review.

Conclusion

The utility of evidence synthesis reports can be enhanced by developing tools that support decisions at two levels, the health system level and the clinical encounter level. These tools provide decision-makers with contextual and implementation information required for decision-making. Current EPC reports should consider engaging health system representatives, patients, methodologists and experts and developing these tools. Topics that deal with management strategies (diagnosis and treatment) are particular areas in need for tools to compliment evidence synthesis tools.

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Abbreviations and Acronyms

CBT	Cognitive Behavioral Therapy
EPC	Evidence-based Practice Centers
EtD	Evidence to Decision